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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,839	06/15/2000	James Anthony	2629-4017	3097

7590 10/10/2003
Morgan & Finnegan LLP
345 Park Avenue
New York, NY 10154

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/10/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/594,839

Applicant(s)

ANTHONY ET AL.

Examin r

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 and 48-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action (Paper No. 20) filed on May 30, 2003 has been entered and considered.
2. The Supplemental IDS (Paper No. 19) filed on December 17, 2002 has been entered.
3. The instant application is filed on June 15, 2000, which claims no priority date.
4. Claims 1-55 are pending. Non-elected claim 47 is withdrawn from consideration.

Response to arguments

5. Applicants' response to the office action (Paper No. 20) is fully considered and found persuasive.
6. With reference to the rejection made in the previous office action under 35 USC 102(b) and 102(e), Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment and arguments and new grounds of rejection.
7. With reference to the rejection made in the previous office action under 35 USC 103(a), Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment arguments and new grounds of rejection.

New Grounds of rejections

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-46 and 48-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite over the recitation of "capable of

Art Unit: 1637

hybridizing" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited set of probes have the potential to hybridize or do in fact do hybridize the recited target nucleic acid which is to be detected. Amendment of the claim to read, for example, "which hybridizes" would obviate this rejection.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 40 rejected under 35 U.S.C. 102(b) as being anticipated by Nathan et al.

(USPN. 6,057,099).

Natan et al teach a method of claims 1, and 40, of detecting a target nucleic acid comprising:

(a) hybridizing a target nucleic acid sample (DNA or RNA) (see column 2, lines 56-57) to a capture sequence probe (first oligonucleotide) and a signal sequence probe (second oligonucleotide probe) to form a double-stranded hybrids between said probes and the target nucleic acid, wherein capture probe and signal probe hybridize with the said target nucleic acid at non-overlapping regions and said probes do not hybridize with each other, and the said signal probe is unlabeled and said hybridization forms a sequence probe-target hybrid (see column 20, lines 51-67, column 21, lines 1-6);

(b) adding a blocker to the hybridization reaction, where in said blocker hybridizes to excess non-hybridized capture probe sequences or signal probe sequences (see column 5, lines 31-63, column 21, lines 7-24);

(c) capturing the sequence probe:target hybrid to form a bound hybrid (see column 21, lines 25-33);

(d) detecting the bound hybrid (see column 21, lines 34-36).

Natan et al. also teach that the method comprises formation of RNA-DNA hybrid (see column 6, lines 20-23). Thus the disclosure of Nathan et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1637

Claims 2-39, 41-46 and 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Natan et al. (USPN. 6,057,099) and in view of Shah et al. (USPN. 5,629,156).

Natan et al teach a method of claims 2-39, 41-46, and 48-55, of detecting a target nucleic acid comprising:

(a) hybridizing a target nucleic acid sample (DNA or RNA) (see column 2, lines 56-57) to a capture sequence probe (first oligonucleotide) and a signal sequence probe (second oligonucleotide probe) to form a double-stranded hybrids between said probes and the target nucleic acid, wherein capture probe and signal probe hybridize with the said target nucleic acid at non-overlapping regions and said probes do not hybridize with each other, and the said signal probe is unlabeled and said hybridization forms a sequence probe-target hybrid (see column 20, lines 51-67, column 21, lines 1-6);

(b) adding a blocker to the hybridization reaction, where in said blocker hybridizes to excess non-hybridized capture probe sequences or signal probe sequences (see column 5, lines 31-63, column 21, lines 7-24);

(c) capturing the sequence probe:target hybrid to form a bound hybrid (see column 21, lines 25-33);

(d) detecting the bound hybrid (see column 21, lines 34-36).

Natan et al. also teach that the method comprises formation of RNA-DNA hybrid (see column 6, lines 20-23). However, Nathan et al. did not teach immobilization of the probes and detecting the probe: target hybrid by using an antibody.

Shah et al. teach a method of claims 2-39, 41-46, and 48-55, detecting a target nucleic acid wherein Shah et al. disclose that the method comprises hybridizing a target nucleic acid (DNA or

RNA) to a capture probe and a detector probe (signal probe), and detecting the bound hybrid (see column 7, lines 17-29, column 3, lines 60-67, column 4, lines 1-51, and column 6, lines 30-57). Shah et al. also teaches immobilization of capture probe on to a solid support (see column 4, lines 29-32); The capture or release using first and second capture probes can be performed in either order (simultaneously or sequentially) (see column 6, lines 58-65). Further Shah et al. teach use of dA-tailed probes (bridge probes) which will bind to both target and dT derivitized supports such that the binding is stronger to the targets than the supports (see column 8, lines 44-54); capture probes biotinylated at both ends (column 9, lines 58-67); the capture probe and the detector probe distance when hybridized to a target comprises less than 3.0kb (see column 9, lines 31-57, see base pair distance of SEQ ID nos.1-4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting a target nucleic acid as taught by Nathan et al. with the method of Shah et al. because Shah et al. states that 'dual capture methods are compatible with conventional sandwich hybridization assays, applicable equally well to assays for DNA and RNA targets. Nucleic acid probes and supports are readily be constructed with the binding characteristics required for dual capture"(see column 8, lines 15-42). In order to reduce signal to noise ratio in hybridization assays involving DNA-protein interaction, an ordinary practitioner would have been motivated to modify the method of detecting a target nucleic acid as taught by Nathan et al. by incorporating the parameters or limitations as taught by Shah et al., since inclusion of said limitations in hybridization assay would improve sensitivity and specificity of detecting a target nucleic acid which results in an improved detection method.


Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
October 7, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER